This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

COMPARISON CHART

1996 QUALITY SYSTEM REGULATION
VERSUS
1978 GOOD MANUFACTURING PRACTICES REGULATION
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ANSI/ISO/ASQC Q9001-1994 AND ISO/DIS 13485:1996

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